

***Remarks***

***I. Status of the Claims***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 7 and 30-40 are pending in the application, with claims 1, 7 and 30 being the independent claims. Claims 2-6 and 8-29 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 1 and 7 have been amended to incorporate elements from cancelled dependent claims, while claim 30 has been rewritten as an independent claim incorporating elements from cancelled claim 9, from which it originally depended. New claims 31-40, which recite species from the Markush group presented in original claim 6, are sought to be added. Accordingly, these changes introduce no new matter and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***II. Election/Restriction***

Applicants wish to thank the Examiner for rejoining claim 30 with claims 1-8 for purposes of examination. *See* Office Action at page 2. The Examiner has maintained that claims 9-29 are, however, drawn to separate inventions from those of claims 1-8 and 30 and has withdrawn claims 9-29 from consideration as being drawn to non-elected inventions. *Id.* Solely to advance prosecution, Applicants have cancelled claims 9-29.

Applicants reserve the right to file a divisional application directed to the subject matter of claims 9-29.

***III. Objection to the Specification***

The Examiner has objected to the specification for failing to comply with 37 C.F.R. § 1.821(d). *See* Office Action at page 3. Applicants have amended the specification to insert the omitted SEQ ID NO., and therefore the present specification complies with 37 C.F.R. § 1.821(d). This amendment to the specification does not introduce new matter.

The Examiner has also objected to the specification for a typographical error on page 63. *Id.* Applicants have amended the specification accordingly. This amendment to the specification does not introduce new matter.

Applicants have, therefore, accommodated the Examiner's objections to the specification and respectfully request that the Examiner reconsider and withdraw the objections.

***IV. Objection to the Claims***

The Examiner has objected to claim 6 for the omission of a comma. *See* Office Action at page 4. Claim 6 has been cancelled, rendering moot the objection. Further, the objection cannot be applied to the present claims in view of the amendments to the claims. Applicants respectfully request withdrawal of the objection.

***V. Rejections Under 35 U.S.C. § 112, Second Paragraph***

The Examiner has rejected claims 1-8 and 30 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. *See* Office Action at pages 4-6, §§ 10-13. Applicants respectfully traverse the rejections. However, solely to advance prosecution and not in acquiescence to the rejections, the claims have been amended. Claims 2-6 and 8-29 have been cancelled, rendering moot the rejection of those claims. Claims 1, 7 and 30 have been amended, and claims 31-40 are new. Applicants respectfully traverse the several rejections under 35 U.S.C. § 112, second paragraph, as they may have been applied to the present claims, and will address each of the Examiner's grounds of rejection in turn.

**(a) Section 10**

The Examiner has rejected claims 1-8 and 30 under 35 U.S.C. § 112, second paragraph, asserting that "it is not clear what the relationship is between the viral envelope protein and the stabilizing peptide, or what is being referred to by the phrase 'structural intermediates.'" Office Action at page 4, § 10.

The relationship between the viral envelope protein and the stabilizing peptide is clearly set forth in the specification including, *inter alia*, page 11, line 21 to page 12, line 26; page 13, line 18 to page 15, line 21; and Figures 1-5. However, solely to advance prosecution and not in acquiescence to the rejection, the claims have been amended and recite that the stabilizing peptide associates with a viral envelope protein. Accordingly, this aspect of the rejection has been overcome.

The phrase “structural intermediate(s)” is used throughout the specification in the context of protein conformational changes that occur during viral fusion and entry. *See* Specification at pages 4, 8, 9, 11-14, 17-20, 28, Figures 1 and 4-6, and the originally filed claims. In view of the specification, and the knowledge available to those of ordinary skill in the art, the phrase as used in the claims is not indefinite.

In addition, the present claims are drawn to structural intermediates that occur in gp41 and/or gp120 in the presence of soluble CD4. Figures 1 and 4-6 illustrate how the formation of structural intermediates in the gp41/gp120 complex are necessary for HIV fusion and entry, and how peptides are believed to disrupt the formation of these structural intermediates. For at least these reasons, the phrase “structural intermediates” in the present claims is not indefinite to those of ordinary skill in the art.

For at least these reasons, reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**(b) Section 11**

The Examiner has rejected claims 1-5, 7, 8 and 30 under 35 U.S.C. § 112, second paragraph, asserting that:

These claims read on compositions comprising a viral particle or viral envelope protein and a stabilizing protein that is “effective to disrupt formation of one or more structural intermediates necessary for viral fusion and entry.” It is unclear what is meant by the quoted phrase. There is no indication of what is meant by a “structural intermediate” in the claim. It is unclear if such structural intermediates relate in some fashion to the viral particles or envelope proteins also present in the claim, or some other structural intermediate involving the stabilizing peptides is intended.

Office Action at page 5, § 11. Applicants respectfully traverse this rejection. First, Applicants reiterate and incorporate herein Applicants' earlier remarks regarding the rejection made in § 10 of the Office Action. For the same reasons cited above, therefore, the phrase "structural intermediates" in the present claims is clear to those of ordinary skill in the art. Second, in making the present rejection the Examiner has not rejected claim 6, which depended from and therefore further limited claim 1. As limitations of the original claim 6 have been incorporated into the present claims they should therefore not be held indefinite. For at least these reasons, reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**(c) Section 12**

The Examiner has rejected claims 1-6 under 35 U.S.C. § 112, second paragraph, for recitation of "capable of associating with." Office Action at pages 5-6, § 12. The language which forms the basis of the rejection has been replaced with the phrase "associates with," accommodating the Examiner's rejection. Reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**(d) Section 13**

The Examiner has rejected claim 6 under 35 U.S.C. § 112, second paragraph, alleging that recitation of a stabilizing peptide that is "functionally equivalent" to a peptide of any one of SEQ ID NOs: 1-7 and 9 is indefinite. Applicants respectfully disagree, as the specification provides teachings sufficient for a person of ordinary skill

in the art to determine if a peptide was functionally equivalent to the reference peptides. Accordingly, the term is not indefinite. However, solely to advance prosecution and not in acquiescence to the Examiner's rejection, the claims have been amended and the present claims do not recite the language which forms the basis for this rejection. Reconsideration and withdrawal of this aspect of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**(e) Summary**

For at least the above reasons all of the rejection under 35 U.S.C. § 112, second paragraph, are traversed, accommodated or rendered moot. Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph, as they may have been applied to the present claims.

***VI. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description***

The Examiner has rejected claims 1-8 and 30 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action at pages 7-12, § 14-16. The first aspect of this rejection is that the scope of the claims allegedly exceeds that provided by the specification by encompassing a genus comprising any viral envelope protein and any stabilizing peptide capable of disrupting the formation of structural intermediates. *See* § 15. The second aspect of the rejection is that the claims encompass any stabilizing peptide against the gp41 glycoprotein, including fragments, functional equivalents, homologues and analogues of

SEQ ID NO:1, and the claim scope therefore allegedly exceeds the scope provided by the specification. *See* § 16. Applicants respectfully traverse both aspects of the rejection.

Nevertheless, solely to advance prosecution and not in acquiescence to the rejection, Applicants have amended the claims. The present claims encompass HIV viral envelope proteins gp41 and gp120, and stabilizing peptides recited in the Markush group. The claimed genus is literally recited in originally filed application and is within the scope which the Examiner has indicated is supported by the specification. *See* §§ 15 and 16. Accordingly, the Examiner's rejection has been accommodated and Applicants respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. § 112, first paragraph, written description.

***Rejections Under 35 U.S.C. § 102***

The Examiner has rejected claims 1-8 and 30 under 35 U.S.C. §§ 102(b) or 102(e) over several cited references. *See* Office Action at pages 12-16, §§ 17-23. Applicants respectfully traverse the rejections. However, solely to advance prosecution, and not in acquiescence to the rejections, the claims have been amended. As claims 2-6 and 8 have been cancelled, that portion of the rejections applied to those claims is rendered moot. Applicants respectfully traverse the remaining portions of the rejections as they may have been applied to present claims 1, 7 and 30-40, and will address each of the Examiner's grounds of rejection in turn.

The claims, as amended, require soluble CD4 as an element in the composition of claims 1 and 31, as an element in the method of claims 7 and 32, and as an element in the

process of claims 30 and 33-40. In addition, all claims recite particular stabilizing peptides but do not recite DP-178 as such a stabilizing peptide.

Rimsky *et al.* (J. Virol. 72: 986-993, "Rimsky") does not disclose a composition comprising soluble CD4, nor the use of soluble CD4 in a method of making immunogenic compositions. The disclosure of Rimsky is also limited to DP-178 (SEQ ID NO:1), and so cannot be applied to the present claims. Accordingly, Rimsky does not teach all elements of the present claims and thus does not anticipate the present claims.

Kliger *et al.* (J. Mol. Biol. 295: 163-168, "Kliger") discloses methods and compositions utilizing synthetic peptides and DP178. Kliger does not disclose a composition comprising whole gp41, soluble CD4 *or* a stabilizing peptide other than SEQ ID NO:1, nor the use of these elements in methods of making immunogenic compositions. The Examiner has also indicated that Kliger does not require that the stabilizing protein is *associated* with the envelope proteins. For at least these reasons Kliger therefore does not anticipate the present claims.

Wild *et al.* (WO 94/02505, "Wild") does not disclose a composition comprising soluble CD4, nor the use of soluble CD4 as part of a method of making immunogenic compositions. Accordingly, Wild does not anticipate the present claims.

Bolognesi *et al.* (WO 94/28920, "Bolognesi") also does not disclose a composition comprising soluble CD4, nor the use of soluble CD4 as part of a method of making immunogenic compositions. Accordingly, Bolognesi does not anticipate the present claims.

Furata *et al.* (Nat. Struct. Biol. 5:276-279, "Furata") is limited to compositions and methods comprising SEQ ID NO:1, and does not disclose compositions comprising



other stabilizing peptides, or the use of other stabilizing peptides in methods of making immunogenic compositions. Accordingly, Furata does not anticipate the present claims.

Root *et al.* (US 2001/0047080, "Root") discloses compositions of a "5-helix molecule" derived from fragments of gp41, complexed with a C-peptide that is allegedly a functional equivalent of SEQ ID NO:1. *See* Office Action at § 23. However, Root does not disclose a composition that comprises soluble CD4 or the use of whole gp41. Root also does not disclose the use of soluble CD4 *or* whole gp41 *or* the peptides recited in the claims in making immunogenic compositions. Accordingly, Root does not anticipate the present claims.

For at least the above reasons, the presently proposed claims are not anticipated by any of the cited references. Reconsideration and withdrawal of each of the rejections under 35 U.S.C. §§ 102(b) and 102(e) are respectfully requested. Further, there is no suggestion or motivation found in the cited references to modify any of the references to arrive at the claimed invention.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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